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TOTELLE UNITED	STATES PATENT	AND TRADEMARK OFFICE

IN RE APPLICATION OF:

Warren et al.

CASE:

IOM-P040

PETITION UNDER

37 C.F.R. 1.47(a)

**SERIAL NO.:** 

10/707,793

and RESPONSE TO

NOTICE TO FILE

FILED ON:

January 13, 2004

MISSING PARTS

FOR:

METHODS FOR TREATING

NEOPLASTIC,

ANGIOGENIC, FIBROPLASTIC, AND/OR IMMUNOSUPPRESIVE OCULAR IRREGULARITIES VIA ADMINISTRATION OF METHOTREXATE BASED MEDICAMENTS AND OCULAR

IONTOPHORETIC DEVICES FOR DELIVERING

METHOTREXATE BASED

**MEDICAMENT** 

Office of Petitions Commissioner of Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Commissioner:

If any charges or fees must be paid in connection with the following communication, they may be paid out of our Deposit Account No. 50-0545.

This petition is submitted concurrently with the partially executed Declaration and Power of Attorney and Assignment documents and in Response to the Notice to File Missing Parts, mailed March 12, 2004. The requisite fees are enclosed.

06/16/2004 JADDO1

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FACTOR & LAKE, LTD.	Jody L. Factor	34157
1327 W. Washington Blvd., Suite 5 G/H	Micheal D. Lake	33727
Chicago, IL 60607	William J. Lenz	44208
(312) 226-1818	Jacob D. Koering	51890
(312) 226-1919 (fax)	Nick Lee	54260

This petition is pursuant to 37 CFR 1.47(a), as a named inventor of the above-identified application has not joined in the above-mentioned patent application. Under 37 CFR 1.47(a), a petition to have a Declaration and Power of Attorney accepted in the absence of the signature of one inventor must be accompanied by:

- (1) an oath or declaration by each applicant on his or her own behalf and on behalf of the non-signing joint inventors;
- (2) factual proof that the missing joint inventors refuse to join in the application or cannot be reached after diligent effort;
- (3) the fee set forth in section 1.17(i); and
- (4) the last known addresses of the non-signing joint inventors.

With respect to item (1), attached is the declaration executed by the other inventor other than inventor Hamilton.

With respect to item (2), attached is a declaration of Patricia Denning providing factual proof that the inventor could not be reached after diligent effort.

With respect to item (3), attached is a check which is inclusive of the \$130.00 fee set forth in section 1.17(i).

With respect to item (4), the last known address of Mr. Hamilton is 1622 Park Place, Park City, Utah, 84098.

Attached hereto in support of the Declaration of Patricia Denning are the following documents:

Exhibit A: Patricia Denning's letter dated February 4, 2004 to Steve Hamilton;

Exhibit B: United States Postal Service ("USPS") website print-out confirming delivery of Exhibit A;

Exhibit C USPS website print-out stating that the USPS has no record of Express Mail Tracking No. EI 715 601 495 US;

Exhibit D Patricia Denning's letter dated April 15, 2004 to Steven Hamilton;

Exhibit E Intellectual Property and Invention Agreement and Agreement Not to Compete as executed by Steven Hamilton;

Exhibit F USPS website print-out confirming delivery of Exhibit D; and

Exhibit G USPS website print-out stating that the USPS has no record of Express Mail Tracking No. EI 715 601 456 US.

In light of the foregoing, Applicant respectfully requests the granting of the present petition.

As a clerical matter, Applicant submits that a response to the Notice to File Missing Parts was originally due on May 12, 2004. In turn, Applicant respectfully requests a one-month extension of time up to and including June 12, 2004.

The Notice to File Missing Parts indicated that the oath or declaration was unsigned. As previously stated, Applicant has attached the partially executed Declaration.

In addition, Applicant submits herewith a copy of the Assignment document, Recordation Form Cover Sheet and \$40.00 assignment fee.

Finally, Applicant encloses herewith a check in the amount of \$290.00 corresponding to (1.) Petition fee of \$130.00; (2.) Surcharge for late oath or declaration of \$65.00; (3.) One-month extension of time fee of \$55.00; and (4.) Assignment Recordation fee of \$40.00.

Should anything further be required, a telephone call to the undersigned is respectfully requested to 312-226-1818.

Respectfully Submitted,

FACTOR & LAKE, LTD

Dated: June <u>(()</u>, 2004

Jody L. Factor

Attorney for Applicant

### **CERTIFICATE OF FIRST CLASS MAILING**

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Office of Petitions, Commissioner for Patents, P.O/ Box 1450, Alexandria, VA 22312-1450 on June \_\_\_\_\_, 2004

Jody L Factor



February 4, 2004

Steve Hamilton 1622 Park Place Park City, UT 84098

Re:

U.S. Patent Application on

The Use of 5-Fluorourcil, Delivered by Iontophoresis as an Inhibitor of Cell Proliferation in the Eye, Bulbar and Palpebral Conjunctiva, Eyelid, Peri-Orbital Soft Tissues and Skin

IOMED's File No. IOM-P043

Dear Steve,

In association with the above-identified patent application, IOMED needs to have an executed Assignment and Declaration on file with the USPTO. I have enclosed these documents for your signature along with a copy of the application for your review. I have also enclosed a pre-addressed stamped Express Mail envelope for your convenience in which to return the documents.

Should you have any questions, please feel free to contact Jody Factor at (312) 226-1818. Thank you for your prompt assistance in completing these documents. I hope all is well with you.

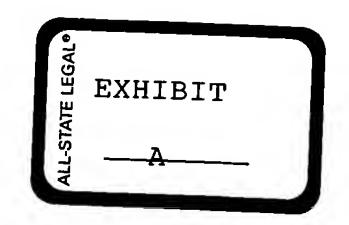
Sincerely,

Patricia L. Denning

Administrative Services Coordinator

/pld

Enclosures





# Track & Confirm

## **Shipment Details**

You entered EI71 5601 487U S

Your item was delivered at 11:49 am on February 06, 2004 in PARK CITY, UT 84098. The item was signed for by J HAMILTON.

Here is what happened earlier:

- NOTICE LEFT, February 05, 2004, 11:35 am, PARK CITY, UT 84098
- ARRIVAL AT UNIT, February 05, 2004, 7:47 am, PARK CITY, UT 84098
- ENROUTE, February 04, 2004, 5:44 pm, SALT LAKE CITY, UT 84122
- ACCEPTANCE, February 04, 2004, 4:11 pm, SALT LAKE CITY, UT 84120

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Via Express Mail

April 15, 2004

Steve Hamilton 1622 Park Place Park City, UT 84098

Dear Steve,

In accordance with the Intellectual Property and Invention Agreement you signed on November 19, 1998, please sign and return the enclosed Assignments and Declarations for the following U.S. patent applications by no later than Wednesday, April 21, 2004.

IOM-P040 Method for Treating Neoplastic, Angiogenic, Fibroblastic, and/or Immunosuppressive Ocular Irregularities Via Administration of Methotrexate Based Medicaments, and Ocular Iontophoretic Devices for Delivering Methotrexate Based Medicaments

IOM-P043 The Use of 5-Fluorourcil, Delivered by Iontophoresis as an Inhibitor of Cell Proliferation in the Eye, Bulbar and Palpebral Conjunctiva, Eyelid, Peri-Orbital Soft Tissues and Skin

I have enclosed a pre-addressed Express Mail envelope for your convenience. Should you have any questions, please feel free to contact Jody Factor at (312) 226-1818 or me at 975-1191 ext. 206.

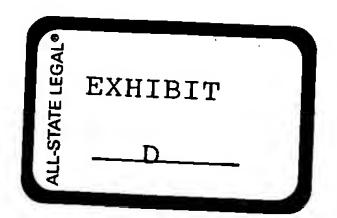
Sincerely

Patricia L. Denning

Administrative Services Coordinator

/pld

**Enclosures** 

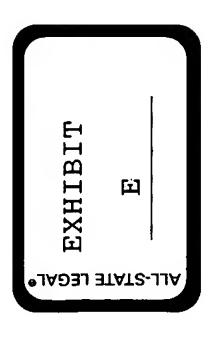


# INTELLECTUAL PROPERTY AND INVENTION AGREEMENT AND AGREEMENT NOT TO COMPETE

THIS AGREEMENT is executed effective November 19, 1998, by and between the undersigned employee ("Employee"), and IOMED, Inc. ("IOMED").

IOMED's activities and business utilize trade secrets, proprietary and confidential information, including, but not limited to, business plans, projections and financial information, and other intellectual property, to which Employee will have access. In consideration of Employee's continued or future employment with IOMED, Employee and IOMED mutually agree to the following:

- 1. a. <u>Non-Disclosure of Intellectual Property</u>. During the term of employment, and at all times thereafter, Employee will not, except in promoting the business of IOMED and performing the duties of Employee's employment, use or disclose, directly or indirectly, any of IOMED's Intellectual Property (as that term is defined below) without IOMED's written consent.
- b. <u>Definition of Intellectual Property</u>. As used in this Agreement, the term "Intellectual Property" shall mean all information disclosed to or known by Employee as a consequence of Employee's employment with IOMED which is not generally known to the public or in the industry in which IOMED does business, or in which it may become engaged in the future, concerning IOMED's products, processes, formulas, designs, plans, projections, financial condition or position, business plans, customer lists and services, including, but not limited to, information relating to research, development, inventions, manufacturing, purchasing, engineering and/or marketing.
- c. Return of Intellectual Property. Upon termination of Employee's employment with IOMED, Employee agrees to immediately return to IOMED all documents, records, data, computer disks, notebooks, and drawings, which contain or reflect Intellectual Property, and all other repositories of Intellectual Property, including all copies thereof, whether prepared by Employee or by others.
- 2. Inventions. Employee hereby agrees to keep IOMED informed of any and all inventions, designs, formulas, works of authorship, compositions of matter and discoveries of any type (hereinafter the "Inventions") made, conceived of or developed by Employee, alone or in conjunction with others, which result from any work Employee may do during, and for six (6) months following the termination of, Employee's employment with IOMED, and which may or may not relate to IOMED's activities or to those of affiliated companies. All such inventions shall be submitted on IOMED's standard Invention Disclosure form for review by IOMED's Patent Committee. It shall be IOMED's policy to release to Employee any such inventions determined by the Patent Committee not to be conceived of or developed on IOMED time, or using IOMED resources, or related to IOMED's activities. The Inventions determined by the Patent Committee to be conceived of or developed on IOMED time, or using IOMED resources, or related to IOMED's activities, shall be and shall remain the property of IOMED or its nominees, whether patented, copyrighted or not, and Employee shall, without charge to IOMED, assign, and hereby agrees to assign, to IOMED all right, title and interest in and



to the Inventions and copyrights. Upon request, Employee will immediately execute, acknowledge, and deliver any instruments confirming IOMED's complete ownership of the Inventions.

Employee will keep and maintain adequate and current written records of all the Inventions, in the form of notes, sketches, drawings and reports relating thereto, which records shall be and remain the property of IOMED, and shall not be removed from the premises of IOMED without permission, and shall be made available at all times to IOMED.

- 3. Agreement Not to Compete. During the term of Employee's employment with IOMED, and for a period of twelve (12) months after the termination, for any reason, of Employee's employment with IOMED, Employee covenants that he/she shall not, in any manner, directly or indirectly, as an employee, owner, proprietor, principal, partner, officer, director, stockholder, member, agent or representative, invest, engage, participate or become interested in, affiliated or connected with, or otherwise render services to, any person or organization engaged in the ownership or operation of any business that is the same as, similar to, or in competition with Employer's business, anywhere within Utah. This prohibition, however, shall not prohibit Employee from purchasing or owning stock in a publicly traded corporation as long as Employee takes no part in the management, control or operation of said corporation. Employee acknowledges and agrees that the time period, geographic area, and scope of activity outlined in this provision are reasonable and are necessary to protect the Intellectual Property and the goodwill of IOMED. However, if this Agreement Not to Compete is determined by a court of competent jurisdiction to be invalid or unenforceable for any reason, such Agreement shall be interpreted to extend over the maximum period of time, geographical area and scope of activity as to which it is valid and enforceable as determined by such court in such action.
- 4. Representations and Warranties of Employee. Employee hereby represents and warrants to IOMED and specifically agrees that:
- a. Neither the execution of this Agreement by Employee nor the performance by Employee of his duties of employment constitute a breach of any agreement or covenant not to compete, confidentiality agreement or any other contract to which Employee may be subject.
- b. IOMED shall have the right to disclose the obligations imposed upon Employee by this Agreement to future or prospective employers and/or business associates of Employee.
- c. The representations, warranties and agreements of Employee, as set forth herein, shall survive the execution of this Agreement.
- 5. Remedies. In the event of a breach or threatened breach of this Agreement, IOMED shall be entitled to an injunction restraining or otherwise prohibiting Employee from disclosing any Intellectual Property and/or from rendering any services to a competitive business and/or from using any of the Inventions in a way which is inconsistent with IOMED's ownership thereof. In addition to its right to pursue such

injunctive relief, IOMED may pursue any other remedies available for such breach or threatened breach, including the recovery of monetary damages from Employee.

- 6. Binding Effect. This Agreement shall be binding upon the parties hereto and upon their respective executors, administrators, legal representatives, successors and assigns.
- 7. Applicable Law. This Agreement shall be governed by the laws of the State of Utah, without giving effect to the choice-of-law rules thereof. If any provision of this Agreement is declared void, the remaining provisions shall remain in full force and effect.
- 8. <u>Final Agreement</u>. This Agreement supersedes all previous agreements, written or oral, relating to the subject matter hereof and shall not be changed orally. This Agreement will not be affected by any present or future policy statement issued by IOMED.
- 9. Attorney's Fees. If either party engages an attorney in connection with a breach or threatened breach of this Agreement, or to otherwise enforce its terms, the prevailing party in the controversy shall be entitled to recover his/her or its reasonable attorney's fees.

In witness whereof, the parties have executed this Agreement effective on the date first set forth above.

IOMED, Inc.	A 1
By: Margalion De	
Its:	Steve Hamilton

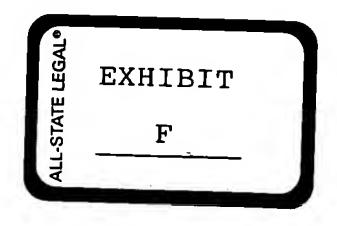


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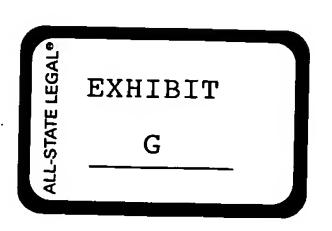
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# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

RE APPLICATION OF:

Warren et al.

CASE:

IOM-P040

**SERIAL NO.:** 

10/707,793

FILED ON:

January 13, 2004

FOR:

METHODS FOR TREATING NEOPLASTIC, ANGIOGENIC, FIBROPLASTIC, AND/OR

**IMMUNOSUPPRESIVE OCULAR** 

IRREGULARITIES VIA ADMINISTRATION OF METHOTREXATE BASED MEDICAMENTS AND OCULAR IONTOPHORETIC DEVICES FOR DELIVERING METHOTREXATE BASED

**MEDICAMENT** 

# **DECLARATION OF PATRICIA DENNING**

The Commissioner of Patents P.O. Box 1450 Alexandria, VA 22313-1450

## Dear Commissioner:

- I, Patricia Denning, a citizen of the United States of America, declare that:
- I am an employee of Iomed, Inc., having a principle place of business at 2441 South 3850 West, Suite A, Salt Lake City, Utah, 84120-9941.
- 2. I am the Administrative Services Coordinator at Iomed, Inc.
- 3. On February 4, 2004, I sent a letter via the United States Postal Services (USPS) Express Mail Service (Tracking Number EI 715 601 487 US) to Steven Hamilton at 1622 Park Place, Park City, Utah, 84098, his last known address, enclosing a copy of the Application for his review along with the corresponding Declaration and Assignment documents for his execution. In addition, a pre-addressed stamped Express Mail envelope (Tracking Number EI 715 601 495 US) was also enclosed with the aforementioned letter.
- 4. According to the USPS website, the package was delivered on February 6, 2004 and signed for by J. Hamilton.

- 5. On or around April 14, 2004, I checked the USPS website for the Tracking Number EI 715 601 495 US whereby indicating that the above referenced preaddressed envelope was not sent back to Iomed.
- 6. As still no response had been received, on April 15, 2004, I transmitted a copy of the Intellectual Property and Invention Agreement as signed by Mr. Hamilton along with a second copy of the Assignment and Declaration documents for his execution via USPS Express Mail service (Tracking Number EI 715 601 460 US) again enclosing a pre-addressed USPS Express Mail envelope (Tracking Number EI 715 601 456 US).
- 7. On April 22, 2004, I checked the USPS website which indicated that the USPS unsuccessfully attempted delivery on April 19, 2004, and left a notice stating the attempted delivery and requesting instructions for re-delivery or pick-up at the Post Office.
- 8. On April 26, 2004, I checked the USPS website again and was informed that the package was delivered and signed for by J. Hamilton.
- 9. On May 4, 2004, as still no response was received, I checked the USPS website and was informed that the preaddressed enveloped identified in Paragraph 6 hereinabove (Tracking Number EI 715 601 456 US) had not been sent.
- 10. In addition to the aforementioned attempts to receive the executed Assignment and Declaration by Mr. Hamilton, I have made numerous attempts at reaching him telephonically to inquire as to the status of these documents. All of such telephone calls remain unreturned.
- As of June 8, 2004, we have been unable to secure the complete execution of the Declaration and Assignment documents.
- 12. All statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and, further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under ' 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent resulting therefrom.

DATED THIS 8th day of June, 2004

SIGNATURE Pátricia L. D